



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Re Patent Application of:
Bruce A. Malcolm, et al.

Examiner: To Be Assigned

Serial No.: 10/679,987

Group Art Unit: To Be Assigned

Filed: October 7, 2003

Atty. Docket No.: JB01587

For: CONTINUOUS NON-RADIOACTIVE:
POLYMERASE ASSAY

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Pursuant to Rule 56, it is requested that the documents listed on the accompanying PTO-1449 Form be considered and made of record in the above-identified patent application. Copy(ies) of these references ☒ are attached ☐ were filed in related application U.S. Serial No(s) _____ filed _____, respectively.

(b) ☒ No fee is believed due because:

- ☐ This Information Disclosure Statement is being filed within three (3) months of the filing date of the application.
- ☐ This Information Disclosure Statement is being concurrently filed with the above-identified application.
- ☐ This Information Disclosure Statement is being concurrently filed with a Request for Continued Examination (RCE).
- ☒ This Information Disclosure Statement is being filed prior to the mailing of a first Office Action on the merits.

(c) ☐ This Information Disclosure Statement is being filed before the mailing date of any final action, notice of allowance or an action that otherwise closes prosecution; and

- ☐ Each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- ☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement; or

☐ The Commissioner is hereby authorized to charge the requisite fee listed on the attached Fee Transmittal Sheet.

(d) ☐ This Information Disclosure Statement is being filed on or before the payment of the issue fee; and

- ☐ Each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- ☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement; and
- ☐ The Commissioner is hereby authorized to charge the requisite fee listed on the attached Fee Transmittal Sheet.
- ☒ The Commissioner is hereby authorized to charge any additional fees which may be required for this Information Disclosure Statement, or credit any overpayment to Deposit Account No. **19-0395**, Patent Case No. **JB01587**. A DUPLICATE COPY OF THIS SHEET IS ATTACHED.

Respectfully submitted,

SCHERING-PLOUGH CORPORATION

Dated: **January 16, 2004**

By:

Karen E. Brown
Karen E. Brown

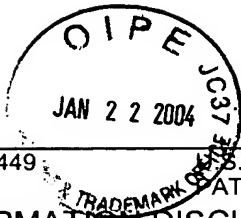
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I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST CLASS MAIL IN AN ENVELOPE ADDRESSED TO COMMISSIONER FOR PATENTS, P.O. BOX 1450, ALEXANDRIA, VIRGINIA 22313-1450 ON January 16, 2004
(DATE OF DEPOSIT)

KAREN E. BROWN, REG. NO. 43,866
(REGISTERED REPRESENTATIVE)

Karen E. Brown 1/16/04
(SIGNATURE AND DATE)



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| FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary) | ATTY. DOCKET NO.: JB01587 | SERIAL NO.: 10/679,987 |
| | APPLICANT: Bruce A. Malc Im, et al. | |
| | FILING DATE: 10/07/2003 | GROUP: |

U.S. PATENT DOCUMENTS

| *EXAMINER INITIAL | | DOCUMENT NUMBER | DATE | NAME | CLASS | SUB- CLASS | FILING DATE IF APPROPRIATE |
|----------------------|----|--------------------|----------|----------------------|-------|---------------|-------------------------------|
| | AA | 6,210,981 B1 | 04/03/01 | Birdsley, et al. | 438 | 9 | |
| | AB | 6,383,768 B1 | 05/07/02 | De Francesco, et al. | 435 | 15 | |
| | AC | 6,258,568 B1 | 07/10/01 | Nyren | 435 | 91.1 | |

FOREIGN PATENT DOCUMENTS

| | | DOCUMENT NUMBER | DATE | COUNTRY | CLASS | SUB- CLASS | TRANSLATION YES | NO |
|--|--|--------------------|------|---------|-------|---------------|--------------------|----|
| | | | | | | | | |

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

| | | |
|--|----|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | AD | Ferrari, et al., "Characterization of Soluble Hepatitis C Virus RNA-Dependent RNA Polymerase Expressed in <i>Escherichia coli</i> ," <i>Journal of Virology</i> 73 (2):1649-1654 (Feb. 1999) |
| | AE | Lohmann, et al., "Biochemical Properties of Hepatitis C Virus NS5B RNA-Dependent RNA Polymerase and Identification of Amino Acid Sequence Motifs Essential for Enzymatic Activity," <i>Journal of Virology</i> 71 (11):8416-8428 (Nov. 1997) |
| | AF | Lohmann, et al., "Biochemical and structural analysis of the NS5B RNA-dependent RNA polymerase of the hepatitis C virus," <i>Journal of Viral Hepatitis</i> 7 :167-174 (2000) |
| | AG | Nyrén, et al., "Enzymatic method for continuous monitoring of inorganic pyrophosphate synthesis," <i>Analytical Biochemistry</i> 151 (2):504-509 (Dec. 1985) |
| | AH | Nyrén, P., "Enzymatic method for continuous monitoring of DNA polymerase activity," <i>Analytical Biochemistry</i> 167 (2):235-238 (Dec. 1987) |
| | AI | Nyrén, et al., "Detection of Single-Base Changes Using a Bioluminometric Primer Extension Assay," <i>Analytical Biochemistry</i> 244 :367-373 (1997) |
| | AJ | Park, et al., "A nonisotopic assay method for hepatitis C virus NS5B polymerase," <i>Journal of Virological Methods</i> 101 :211-214 (2002) |
| | AK | Reigadas, et al., "HCV RNA-dependent RNA polymerase replicates <i>in vitro</i> the 3' terminal region of the minus-strand viral RNA more efficiently than the 3' terminal region of the plus RNA," <i>Eur. J. Biochem.</i> 268 :5857-5867 (2001) |
| | AL | Ronaghi, et al., "Real-Time DNA Sequencing Using Detection of Pyrophosphate Release," <i>Analytical Biochemistry</i> 242 :84-89 (1996) |
| | AM | Vassiliou, et al., "Exploiting Polymerase Promiscuity: A Simple Colorimetric RNA Polymerase Assay," <i>Virology</i> 274 :429-437 (2000) |
| | AN | Zhong, et al., "De Novo Initiation of RNA Synthesis by Hepatitis C Virus Nonstructural Protein 5B Polymerase," <i>Journal of Virology</i> 74 (4):2017-2022 (Feb. 2000) |
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| EXAMINER | DATE CONSIDERED |
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.